IN THE CLAIMS

Please amend claims 6, 7, 9, 10, 15, 17-21, 23, and 27 as follows.

1. Cancelled

2. (previously amended) A formulation according to claim 10 wherein galantamine is in the form of galantamine hydrobromide (1:1).

3. (previously amended) A formulation according to claim 10 wherein the water soluble excipient is a film forming polymer.

4. (Original) A formulation according to claim 3 wherein the water soluble film forming polymer is a polymer that has an apparent viscosity of 1 to 100 mPa.s when dissolved in a 2 % aqueous solution at 20°C solution.

5. (Original) A formulation according to claim 4 wherein the water soluble polymer is selected from the group comprising
   - alkylcelluloses such as methylcellulose,
   - hydroxyalkylcelluloses such as hydroxymethylcellulose, hydroxyethylcellulose,
   - hydroxypropylcellulose and hydroxybutylcellulose,
   - hydroxyalkyl alkylcelluloses such as hydroxyethyl methylcellulose and hydroxypropyl methylcellulose,
   - carboxyalkylcelluloses such as carboxymethylcellulose,
   - alkali metal salts of carboxyalkylcelluloses such as sodium carboxymethylcellulose,
   - carboxyalkylalkylcelluloses such as carboxymethylethylcellulose,
   - carboxyalkylcellulose esters,
   - starches,
   - pectines such as sodium carboxymethylamylopectine,
   - chitine derivates such as chitosan,
   - polysaccharides such as alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, traganth, agar-agar, gummi arabicum, guar gummi and xanthan gummi,
   - polyacrylic acids and the salts thereof,
   - polymethacrylic acids and the salts thereof, methacrylate copolymers,
   - polyvinylalcohol,
   - polyvinylpyrrolidone, copolymers of polyvinylpyrrolidone with vinyl acetate
   - polyalkylene oxides such as polyethylene oxide and polypropylene oxide and copolymers of ethylene oxide and propylene oxide.

6. (Currently amended) A formulation according to claim 5 wherein the water soluble polymer is hydroxypropyl methylcellulose HPMC 2910 with an apparent viscosity of 5 mPa.s when dissolved in a 2 % aqueous solution at 20°C.

7. (Currently amended) A formulation according to claim 6 wherein the weight-by-weight ratio of said hydroxypropyl methylcellulose ~~HPMC 2910 5 mPa.s~~ to galantamine is in the range of 17 : 1 to 1 : 5.

8. (Original) A formulation according to claim 2 wherein galantamine hydrobromide (1:1) and the water soluble, film forming polymer are layered or coated on an inert sphere.

9. (Currently amended) A formulation according to claim 8 wherein the inert spheres are 16-60 mesh (1,180-250 µm) sugar spheres ~~(NF XVII, page 1989)~~.

10. (Currently amended) A controlled release formulation containing galantamine as the active ingredient, characterized in that it comprises particles comprising galantamine or a pharmaceutically acceptable acid addition salt thereof, and a water soluble pharmaceutically acceptable excipient ~~and optionally other pharmaceutically acceptable excipients~~, said particles being coated by a release rate controlling membrane coating wherein the release rate controlling membrane coating comprises a water insoluble polymer and optionally a plasticizer.

11. (Original) A formulation according to claim 10 wherein the water insoluble polymer is ethylcellulose and the plasticizer is selected from the group comprising dibutyl sebacate, diethyl phthalate and triethyl citrate.

12. (Original) A formulation according to claim 11 wherein the weight of the release rate controlling membrane coating ranges from 3 % to 15 % of the uncoated particle.

13. (previously amended) A formulation according to claim 10 wherein a seal coat lies between the drug core and the release rate controlling membrane coating.

14. (previously amended) A formulation according to any one of claims 2 to 13 further comprising a topcoat comprising galantamine and water-soluble polymer.

15. (Currently amended) A formulation according to any of claims ~~2-13~~2 to 13 further comprising a topcoat comprising galantamine and water-soluble polymer and capable of releasing in USP buffer pH 6.8 at 37°C in ~~an Apparatus 2~~ a paddle apparatus ~~(USP 23, <711> Dissolution, pp 1791-1793, paddle,~~ operating at 50 rpm,~~)~~ from 20 to 40 % of the

total amount of galantamine.HBr in 1 hour, and more than 80 % of the total amount of galantamine.HBr in 10 hours.

16. Cancelled

17. (Currently amended) A dosage form according to any of claims ~~2-13~~2 to 13 which delivers a therapeutically effective amount of galantamine to a patient during the 24 hours following a single once daily administration.

18. (Currently amended) A dosage form according to any of claims ~~2-13~~2 to 13 wherein part of the galantamine is present in an immediate release form.

19. (Currently amended) A dosage form according to any of claims ~~1~~2 to 13 wherein part of the galantamine is present in an immediate release form and said immediate release form comprises particles as described in claim ~~1~~10 lacking the release rate controlling membrane.

20. (Currently amended) A dosage form according to any of claims ~~1~~2 to 13 wherein part of the galantamine is present in an immediate release form and said immediate release form comprises immediate release minitablets.

21. (Currently amended) A dosage form according to any of claims ~~1~~2 to 13 wherein part of the galantamine is present in an immediate release form, said immediate release form ~~comprises a controlled release formulation of claim 1~~further comprising a topcoat comprising galantamine and water-soluble polymer.

22. (previously amended) A dosage form according to claim 2-13 providing a mean maximum plasma concentration of galantamine from 10 to 60 ng/ml and a mean minimum plasma concentration from 3 to 15 ng/ml after repeated administration every day through steady-state conditions.

23. (Currently amended) A pharmaceutical package suitable for commercial sale comprising a container, a formulation of galantamine as claimed in claim 10, and associated with said package written matter specifying how said formulation should be administered.

24. (Original) A pharmaceutical package as claimed in claim 23 adapted for titrating a patient who is 'acetylcholine esterase inhibitor'-naïve, characterized in that said package comprises 21-35 daily sequential dosage units of
(a) a first group of 7 to 14 dosage units comprising from 5 to 10 mg galantamine,
(b) a second group of 7 to 14 dosage units comprising from 10 to 20 mg galantamine,

(c) a third group of 7 to 14 dosage units comprising from 15 to 30 mg galantamine, and
(d) optionally a fourth group of 7 dosage units comprising from 20 to 40 mg galantamine.

25. (Original) A pharmaceutical package as claimed in claim 23 adapted for treating a patient who is 'acetylcholine esterase inhibitor'-tolerant, characterized in that said package comprises daily dosage units comprising from 15 to 30 mg galantamine.

26. (previously amended) A process of preparing a formulation according to claim 10 comprising admixing galantamine or a pharmaceutically acceptable salt form thereof with a water soluble excipient to form a drug core, optionally applying a seal coat to the drug core, and thereafter applying the release rate controlling membrane coating.

27. (Currently amended) A method of treating Alzheimer's dementia and related dementias in a human while substantially reducing or ~~(avoiding)~~ the concomitant liability of adverse effects associated with acetyl cholinesterase inhibitors, comprising administering to a human in need of such treatment, a therapeutically effective amount of galantamine in a controlled release formulation as claimed in claim 10, said amount being sufficient to alleviate said Alzheimer's dementia and related dementias, but insufficient to cause said adverse effects.

28. (Original) A method according to claim 27 wherein the related dementia belongs to the group consisting of vascular dementia, Lewy body disease, autism, mental retardation, bipolar disorder psychiatric conditions, disruptive behaviour, attention deficit, hyperactivity disorder, substance abuse, extreme aggression, especially conduct disorder, nicotine cessation and withdrawal.

29. (Original) A method according to claim 27 wherein the adverse effects belong to the group comprising nausea, vomiting, sweating, restlessness, and insomnia.